

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-2058V

MARGARET EDDINGS,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: November 27, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT¹

On December 30, 2020, Margaret Eddings filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the “Vaccine Act”). Petitioner alleges a Table injury - that she suffered a shoulder injury related to vaccine administration (“SIRVA”) after receiving an influenza (“flu”) vaccine on October 23, 2019. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (“SPU”).

¹ Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

After a full review of the evidence, I find it most likely that Petitioner suffered the onset of her shoulder pain within 48 hours of her October 2019 vaccination, and has satisfied all Table requirements for a SIRVA injury, and is otherwise entitled to compensation for her SIRVA.

I. Relevant Procedural History

After the case's initiation and SPU assignment, Respondent filed a Rule 4 Report recommending that entitlement to compensation be denied – primarily because of a failure to establish Table onset. ECF No. 30 at 7-9. I subsequently set deadlines for the filing of any additional evidence and briefs addressing entitlement. ECF No. 31. On March 27, 2023, Petitioner filed a Motion for Ruling on Record in support of this claim. ECF No. 34. On April 14, 2023, Respondent filed an opposition brief maintaining the arguments set forth in his Rule 4 Report that Petitioner has failed to establish a SIRVA Table claim. ECF No. 35. This matter is now ripe for my resolution.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,³ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time-frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

³ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. Section 11(c)(1)(A)(B)(D)(E).

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

III. Relevant Factual Evidence

I have reviewed all evidence filed to date, but limit my discussion below to the medical records and other evidence most relevant to the disputed onset issue. 42 C.F.R. § 100.3(c)(10)(ii); 42 C.F.R. § 100.3(a)(XIV)(B).

A. Records

- Petitioner, a 74-year-old woman, received a flu vaccine in her left deltoid on October 23, 2019. Ex. 1 at 1; Ex. 5 at 6.
- Petitioner's pre-vaccination medical history was significant for multiple conditions, including, but not limited to the following conditions: rheumatoid arthritis, osteoarthritis, Sjoren's syndrome, diverticulitis, knee replacement surgery. See, e.g., Ex. 2 at 27, 34; Ex. 8 at 2-3; Ex. 12 at 93, 95
- On October 29, 2019 (hence six days after her vaccination), Petitioner was seen by her rheumatologist, Gary Craig, M.D., for an "[e]stablished p[atien]t" visit to address her long-term joint pain and rheumatoid arthritis. Ex. 8 at 68. An extensive history of Petitioner's rheumatological issues and other significant medical history is provided in the record. *Id.* Included in the medical history is discussion of her ongoing rip hip pain which she planned to address with an orthopedist. *Id.* Additionally, Petitioner's medications/drug therapy for her rheumatological conditions were discussed and prescriptions renewed. *Id.* at 69, 72-73

A musculoskeletal review was positive for the following: "[j]oint stiffness in the morning. (Stiffness lasts 20 mins or so). Joint pain. Muscle weakness. Muscle tenderness. [P]ain – neck, hands." Ex. 8 at 71. No report of specific left shoulder or arm pain is contained in this record, although "[m]inor midrange crepitus" is noted in the shoulders on physical examination. *Id.* at 71.

- On November 7, 2019 (now 15 days following Petitioner's vaccination), Petitioner was seen at the office of her primary care provider for a six-month follow-up visit for her numerous long-term medical issues which were discussed, including a

referral and MRI to address her right hip issues. Ex. 12 at 73.⁴ The visit record also includes a “comments” section that documents “*L[eft] arm pain*, all over arthritis pain.” *Id.* at 81 (emphasis added). Additionally, a review of Petitioner’s musculoskeletal systems noted that she was positive for “Joint pain, Neck pain.” *Id.* at 80.

- On November 13, 2019 (21 days post-vaccination), Petitioner was seen by orthopedist Dr. Douglas McInnis for ongoing right hip pain. Ex. 2 at 24. Dr. McInnis states in the record that Petitioner “has a long-term diagnosis of rheumatoid arthritis and Sjogren’s” which she manages with a combination of medications. *Id.* at 25. Dr. McInnis further states that he first met Petitioner “and began discussing the rheumatoid arthritis in her hip more than 4 years ago”, that “in the interim her symptoms have worsened”, and her rheumatologist encouraged her to “initiate consideration and discussion about hip replacement.” *Id.* at 25. Dr. McInnis states that “hip replacement is virtually inevitable” and that it was “appropriate to proceed with hip replacement.” *Id.* at 26. Petitioner did not discuss any shoulder or arm pain at this visit.
- Almost four months later, Petitioner underwent a right hip replacement (arthroplasty) on March 9, 2020. See e.g., Ex. 2 at 21; Ex. 3 at 98. Subsequently, on March 16, 2020, Petitioner commenced physical therapy for her right hip pain post-surgery. Ex. 3 at 98. There are no intervening records from November 2019 to this point mentioning shoulder pain or memorializing efforts to treat it.
- On April 8, 2020 (over five months post vaccination), Petitioner was seen by her PCP, Susan Daugharty-Fowler, MD, for “left shoulder pain f/u [follow-up] and palpitations/tachycardia.” Ex. 12 at 60. The record provides that Petitioner “states she received her flu vaccine on 10/23/2019 from pharmacy into the left shoulder and the injection was given quite high and she felt immediate pain afterwards, unlike any other flu vaccine she has received.” *Id.* She further noted that “[i]t has been painful and sore since then and she now has pain down the left arm and radiating up into the neck.” *Id.* It was noted that she had “tried icing it which is mildly helpful. She was taking tramadol after her recent hip replacement and even this did not seem to provide much benefit for the shoulder.” *Id.*

On examination of the left shoulder, it was noted that Petitioner had a “[d]iffuse tenderness to palpitation,” and “mostly intact but somewhat limited range of motion, main difficulty with internal range of motion.” Ex. 12 at 67. Dr. Daugharty-

⁴ Exhibit 12, located at ECF No. 20-2, is incorrectly paginated as Exhibit 2, although it was correctly identified as Exhibit 12 on the docket sheet, and on Petitioner’s Notice of Filing, filed February 8, 2022. ECF No. 20.

Fowler 's impression was "chronic worsening left shoulder pain initial[] onset after having a flu shot in the arm." *Id.* at 67. Dr. Daugharty-Fowler noted that Petitioner "is quite thin, there is concern for a possible tendon injury based on how she describes the onset of pain." *Id.* at 68.

- On April 13, 2020, returned to see Dr. Daugharty-Fowler for a shoulder injection. It was noted that Petitioner complained of "restricted movement [and was] unable to raise a glass to her face. She is unable to the sleep on the right side d/t [due to] right hip pain noting this is exacerbating the pain in the left shoulder." Ex. 12 at 49. Dr. Daugharty-Fowler administered a steroid injection to Petitioner's left shoulder and indicated that if the injection was not effective physical therapy would be considered. *Id.* at 56-57.
- Subsequently, Dr. Daugharty-Fowler provided an order for Petitioner to receive a left shoulder MRI, which Petitioner underwent on May 13, 2020. The MRI impression included a "[n]ondisplaced posterior superior labral tear" and "[m]oderate subacromial subdeltoid bursitis." Ex. 12 at 47.
- On May 29, 2020, Petitioner was seen for pain in the left shoulder by Jeffrey Lien, PA-C, at her orthopedist's office. Ex. 2 at 17. The record states that Petitioner's "[s]ymptoms began [in] October, 2019." *Id.* Specifically, Petitioner complained of "left shoulder pain after undergoing a flu shot but [sic] was administered 'high' in her shoulder by the practitioner that gave it to her." *Id.* Mr. Lien states that Petitioner "claimed that since that flu shot she has had troubles with her shoulder and the pain emanating from it." *Id.* Petitioner was assessed with left shoulder bursitis and impingement and recommended to undergo physical therapy to work on strengthening. *Id.* at 19.
- Petitioner commenced physical therapy for her left shoulder pain on June 19, 2020. Ex. 3 at 149. The exam notes from her first PT visit states that she "reports that the initial symptoms began after getting a flu shot this winter. She believes the injection was administered incorrectly as she has experienced pain and with movement ever since receiving it." *Id.*
- Thereafter, Petitioner's medical records indicate that she continued to treat for her left shoulder pain through at least December 11, 2020. Ex. 2 at 4-5. On that date, Petitioner was seen for continued shoulder pain at her orthopedist's office. Mr. Lien observed that "I still do believe the majority of the pain is stemming from impingement/bursitis of the left shoulder. This all stems from a subacromial flu injection that was given to her [approximately] 1 year ago." *Id.* at 5. Mr. Lien administered a third steroid injection at this appointment to treat Petitioner's

shoulder pain, and stated that the next step if her pain persisted would be “arthroscopic intervention.” *Id.* at 5-6.

B. Declaration

Petitioner executed a signed and sworn declaration on February 13, 2023, addressing the onset of her left shoulder pain and delay seeking treatment. Ex. 13. Petitioner states that she had immediate pain upon administration of her October 23, 2019 flu vaccine. Ex. 13, ¶ at 2-3. Petitioner elaborates that a vaccination had “never hurt [her] like that before.” *Id.* Petitioner acknowledges that she had an appointment with her rheumatologist, Dr. Craig six days later on October 29, 2019, and states that she did not report her left shoulder pain as the appointment “was only to discuss medications.” Ex. *Id.* at ¶ 4.

Petitioner further states that on November 7, 2019, she was seen by the nurse practitioner at the office of her PCP. Petitioner told the nurse practitioner “about my shoulder,” but was advised that “this happens a lot of times after the flu shot, but if it does not get better then I should make an appointment to see the doctor.” *Id.*, ¶ 5.

Petitioner explains that she delayed “formal treatment” of her shoulder pain because she “had debilitating hip pain which took priority – eventually requiring a total hip replacement.” Ex. 9, ¶ 6. Petitioner states that between her hip issue, and COVID which delayed her ability to immediately get an appointment, she did not immediately address her shoulder pain. *Id.* Ultimately, Petitioner states that her shoulder pain did not get better and was preventing her from “doing things so I decided I needed to seek treatment.” *Id.*

IV. Findings of Fact

A. Onset

The only disputed factor in this SIRVA Table claim is whether Petitioner experienced the onset of her pain within 48 hours after her October 23, 2019 flu vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii).

Respondent reasonably disputes onset in this case given that Petitioner delayed seeking treatment for her shoulder pain for over five months following her vaccination (although she did at least once report left arm pain much earlier), and despite seeking treatment for other issues in the interim. However, I find that Petitioner’s medical records and declaration collectively establish that her shoulder pain likely began within 48 hours of her vaccination.

As a preliminary matter, it is important to emphasize that the Vaccine Act specifically contemplates that in some cases a special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). The Act elaborates that “[s]uch a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

Delay in treatment can weigh against a favorable onset finding, but is not *per se* dispositive of the issue. For as I have previously observed, “[g]iven the nature of SIRVA injuries, some delays in treatment are common in Program cases.” *Reynolds v. Sec’y of Health & Hum. Servs.*, No. 19-1683V, 2023 WL 3713694, at *6 (Fed. Cl. May 30, 2023) (citing *Winkle v. Sec’y of Health & Human Servs.*, No. 20-485V, 2021 WL 2808993, at *4 (Fed. Cl. Spec. Mstr. June 3, 2021) (“[i]t is common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own” and finding that the onset of the petitioner’s pain occurred within 48 hours of vaccination in spite of a five month delay in seeking treatment)).

Here, Petitioner’s declaration provides a reasonable explanation for her delay seeking treatment for her shoulder pain notwithstanding her intervening medical appointments – and it is corroborated by the medical record. Petitioner acknowledges that she did not report her shoulder pain following her flu shot at her rheumatology appointment six days after her vaccination.⁵ Ex. 9, ¶ 4. But she contends that she *did* report her shoulder pain following vaccination to the nurse practitioner she saw at her PCP office visit on November 7, 2019 (15 days after her vaccination), and was advised by that this was a common occurrence that could be followed up later if it persisted. *Id.*, ¶ 5.

This contention is supported by the corresponding medical record “comments,” which note “*L[eft] arm pain, all over arthritis pain*”⁶ reported at this appointment. Ex. 12 at 81 (emphasis added). Petitioner explains that the nurse practitioner advised her that

⁵ The parties do not agree as to why pain was not discussed. Petitioner states in her declaration this appointment was “was only to discuss medications.” Ex. 9, ¶ 4. Respondent argues this statement is contrary to the medical records, which include evidence of an exam and a review of her history. ECF No. 35 at 7.

⁶ Respondent argues that the left arm pain notation is “ambiguous, as arm (not shoulder) pain is noted in the same context as arthritis pain.” ECF No. 35 at 8. Although this is a fair objection, it remains the case that this pain was specifically reported, and not simply subsumed within the general complaints of arthritic pain. Additionally, it is my experience that petitioners in SIRVA cases frequently use arm and shoulder interchangeably.

shoulder pain post-vaccination happens frequently, and if it did not get better, she should see the doctor. Ex. 9, ¶ 5. Finally (and as Petitioner explains in her declaration), she ultimately delayed “formal treatment” of her shoulder pain because of her more pressing concerns about hip issues – which did in fact result in a surgical procedure. Ex. 9, ¶ 6. The medical records support this statement as well; following a surgical consultation with Dr. McInnis on November 13, 2019, Petitioner underwent hip surgery on March 9, 2020. Ex. 2 at 21, 24-25.

One month after this surgery, Petitioner sought out care specifically for her left shoulder pain, returning to her PCP’s office – who noted she was there for being seen for “shoulder pain f/u” (presumptively in follow-up to her prior report of shoulder pain at her PCP’s office 15 days after her vaccination). Ex. 12 at 60. At this time (still less than six months after Petitioner’s vaccination) the record explicitly documents that Petitioner “states she received her flu vaccine on 10/23/2019 from pharmacy into the left shoulder and the injection was given quite high and she felt immediate pain afterwards, unlike any other flu vaccine she has received”. Ex. 12 at 60. The record further notes that Petitioner’s shoulder “has been painful and sore since then.” *Id.* Thereafter, Petitioner’s sought ongoing treatment for her shoulder pain, consistently associating the onset of her shoulder pain with her vaccination. Ex. 2 at 17 (“[s]ymptoms began [in] October, 2019” and “left shoulder pain after undergoing a flu shot”); Ex. 3 at 149 (“reports that the initial symptoms began after getting a flu shot this winter”); Ex. 2 at 5 (“I still do believe the majority of the pain is stemming from impingement/bursitis of the left shoulder. This all stems from a subacromial flu injection that was given to her [approximately] 1 year ago.”).

Taken as a whole, the evidence weighs in favor of the determination that onset of Petitioner’s shoulder pain occurred within 48 hours of her flu vaccination. 42 C.F.R. §§ 100.3(a)(XIV)(B), (c)(10)(ii). Of course, the delay in treatment still bears on the claim in other regards. If it becomes necessary for me to determine damages in this matter, I will take into consideration the fact that Petitioner’s did not seek treatment for her shoulder, or specifically associate her shoulder pain with her vaccination, until more than five months following her vaccination. Such a lengthy delay demonstrates that Petitioner’s shoulder pain (even if most likely reported to at her visit to her PCP’s office 15 days after her vaccination) was not severe enough to compel Petitioner to seek immediate medical help – and thus undermines a determination that this SIRVA was particularly severe.

B. Other Table Requirements and Entitlement

Petitioner has established all other requirements for a Table SIRVA claim. There is no history of shoulder pain, inflammation, or dysfunction that would explain the post-vaccination injury. 42 C.F.R. § 100.3(c)(10)(i). Petitioner’s “[p]ain and reduced range of

motion [were] limited to the [left] shoulder in which the intramuscular vaccine was administered.” 42 C.F.R. § 100.3(c)(10)(iii). Additionally, there is not preponderant evidence of another condition that would explain the symptoms. 42 C.F.R. § 100.3(c)(10)(iv). However, even if a petitioner has satisfied the requirements of a Table injury or established causation-in-fact, he or she must also provide preponderant evidence of the additional requirements of Section 11(c), *i.e.*, receipt of a covered vaccine, residual effects of injury lasting six months, *etc.* See *generally* § 11(c)(1)(A)(B)(D)(E). But those elements are established or undisputed in this claim. I therefore find that Petitioner is entitled to compensation in this case.

Conclusion

Based on the entire record, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA. Petitioner is entitled to compensation. A Damages Order will issue.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master